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Local formularies

D. John M. Reynolds,[1] Olubunmi Fajemisin[2] & Sara Wilds[3]

[1]Consultant Physician and Clinical Pharmacologist, Oxford University Hospitals NHS Trust, Oxford, [2]Medicines Effectiveness Pharmacist, Oxford University Hospitals NHS Trust, Oxford OX3 9DU, and [3]Primary Care Prescribing Lead Oxfordshire & Buckinghamshire Cluster, Cowley, Oxford OX4 2LH, UK

Correspondence
Dr D. John M. Reynolds, Consultant Physician and Clinical Pharmacologist, Oxford University Hospitals NHS Trust, Oxford OX3 9DU, UK.
Tel.: +44 018 6522 0965
E-mail: john.reynolds@ouh.nhs.uk

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The widespread availability of authoritative guidance on prescribing from a wide variety of international and national bodies calls into question the need for additional local formulary advice. This article describes contemporary local formulary management in the United Kingdom and discusses the areas where local decision making remains valuable. Local formularies can fulfil important roles which justify their continued existence, including ensuring local ownership and acceptance of advice, rapid dissemination of information, responsiveness to local circumstances and service design, sensitivity to local pricing arrangements and close professional links with commissioners, pharmacists and prescribers.

Introduction

Formularies are the basis of the management and governance systems used to influence the range of medicines available within healthcare organizations.

They exist in many primary care organizations and hospitals in the developed world, and within these settings individual departments and General Practices often have their own abbreviated versions tailored to reflect their specific needs. The extent to which these formularies are managed varies considerably – some are simply descriptive lists (in effect pharmacy stock lists) and others are actively managed and used to complement other strategies for ensuring high quality and cost effective prescribing.

Most individual prescribers have their own informal repertoire of drugs with which they feel comfortable, at least insofar as they are familiar with the dosing requirements and the likely common side effects. Straying outside one's usual area of prescribing competence is associated with a high risk of error and so having a 'preferred list of drugs' reinforces familiarity and competence in their use.

Never has there been better access to high quality advice on therapeutics and prescribing (Table 1), and it is not unreasonable to question whether the resources expended on creating and maintaining local formularies is justified. We believe there are however sound reasons for developing and managing a formulary which is specific to an individual organization and these are discussed below.

Table 1
Sources of advice on therapeutics and prescribing

All Wales Medicines Strategy Group	AWMSG
BMJ Clinical Evidence	
British National Formulary	BNF
British National Formulary for Children	BNFC
Drugs and Therapeutics Bulletin	DTB
Hospital Pharmacy Medicines Information Centres	
Local Medicines Management Teams in Primary and Secondary Care Trusts	
MeReC	
National Institute for Health and Clinical Excellence	NICE
National Prescribing Centre	NPC
Royal Colleges and Professional Societies and Organizations	
Scottish Medicines Consortium	SMC

Oversight of formularies in the UK is generally undertaken by Drug and Therapeutics Committees (DTC) in Secondary Care, and Area Prescribing Committees (APC) and PCT Medicines Management Committees in Primary Care. Similar structures exist in many other countries [1–4]. These committees have a broader scope than formulary management alone and most would recognize their remit to reflect a commitment to promote rational, safe and cost efficient use of medicines [1] within their organizations. Ensuring these committees have a transparent process for

formulary management is essential to ensure consistency, credibility and acceptance.

Where then do formularies and formulary committees add value at a local level and how may they be best used to improve the quality of prescribing?

Education and ownership

In any reasonably sized organization, the process of critical analysis of which drugs and formulations should be included in a local formulary demands a considerable amount of information gathering and discussion which in itself has a valuable educational function. Going through a rigorous process is more likely to instil local ownership and improve the adherence to the formulary.

Audit of formulary adherence helps to re-evaluate the decisions around drug choice, and reinforces the rationale for using the drugs which are included. It helps to identify those circumstances where flexibility needs to be exercised and when changes are required. In all but the most restricted areas of prescribing, a static formulary list is unlikely to influence behaviour in a positive way and will rapidly lose its value and we would argue that the formulary evaluation process must include regular review.

Rapid turnaround before national advice is available

One of the major advantages of having a local formulary is that it becomes possible to make changes rapidly as new information becomes available. When new pharmaceuticals are launched and marketed, trends in prescribing (particularly in primary care) can be picked up and new agents or indications can be assessed and formulary choice can be reviewed. National technology appraisal and guidance may take months and even years to come to fruition. In the meantime organizations need guidance to manage the introduction of, and disinvestment from, medicines in the local health economy and individual clinicians need advice to inform their own prescribing practice.

Many products are not sufficiently innovative to trigger national evaluation but nonetheless justify local advice which needs to take into account effectiveness, safety and affordability within the resources available.

Examples include modified release preparations of existing products, new drugs within well established classes (me-too agents), and products with different formulations such as transdermal patches. Some of these may represent poor value for money but others may bring advantages other than simply by being cheaper. For example a 24 h transdermal rivastigmine patch may be useful for patients with moderate Alzheimer's disease with swallowing difficulties or compliance issues who require supervised care with drug administration at home rather having than an oral formulation twice a day. On the on other hand, a modified-release formulation of a drug (like doxazosin), which is intrinsically long-acting might be considered not suitable for the local formulary.

Cost effectiveness

Drug formularies have a major role in the containment of cost within a healthcare setting. In secondary care the agreed formulary list is in effect the list of drugs available as pharmacy stock and as a consequence prescribing off formulary is difficult and the process of obtaining non-formulary drugs is usually well managed.

In primary care however this level of formulary management is not possible as there is no such restriction on the availability of drugs and so adherence to the formulary relies entirely on local engagement from prescribers.

Increasingly, prescribing support software (e.g. ScriptSwitch®) and input by medicines management teams are being commissioned and programmed by primary care organizations. These enable links to GP clinical systems, to provide prescribers with local formulary choices and advice on the latest cost saving, safety and effectiveness issues relating to medicines.

Antibiotic stewardship

One of the few interventions with a sound evidence base for reducing healthcare-associated infection is effective antibiotic stewardship [5]. Limiting excessive antibiotic usage by defining the choice of drug used (avoiding unnecessarily broad spectrum agents), the route of administration, dosage and duration all contribute to reductions in *Clostridium difficile* infection rates [6] and minimize the risks of emergence of antibiotic resistant strains of other organisms. Central to any programme of stewardship is the maintenance and management of a credible antibiotic formulary. Local clinical practice and case mix, resistance rates and the prevalence of different strains of organisms dictate the precise choice of agents available in any given formulary. In order to achieve local ownership it is sometimes necessary to compromise where evidence on suitability between agents is absent or unclear.

Awareness of local circumstances and service design

Technology appraisals and guidance (from NICE, SMC or AWMSG) are of high quality and generally have a strong influence on prescribing. However local formulary committees will be uniquely aware of local circumstances and may reasonably seek to modify or adapt national advice. For example when NICE endorsed the use of GPIIb/IIIa antagonists for use in acute coronary syndromes in the time

between initial presentation and percutaneous coronary intervention (PCI), some hospitals with immediate access to PCI did not feel the need to implement the guidance and these agents were not included on their formularies.

Clearly specialist departments will have different formulary requirements from others and for rare conditions national commissioning may dictate that certain drugs are only available in designated centres, for example the management of primary pulmonary hypertension in adults [7].

Formulary restrictions

Within a formulary it is often necessary to restrict the use of a particular medicine to a specified clinical area or group of clinicians. The reasons for doing this may be:

- Highly technical services requiring special facilities, skills or training, e.g. chemotherapy, anaesthesia, intensive care.
- High cost medicines where decisions about usage rest with experienced clinicians who agree to act as gatekeepers, e.g. antibiotic usage outside first and second line recommendations can be restricted to microbiology and infectious diseases physicians only.
- Medicines of limited value where careful case selection is important to justify use, e.g. ivabradine limited to consultant cardiologist prescribing.
- Certain types of unlicensed medications.

Lack of sufficient familiarity with a medicine or clinical area, e.g. many specialist drugs will be restricted to hospital prescribing and supervision. In some cases locally agreed shared care protocols have been established to support transfer of prescribing to primary care once a patient is stabilized. This shared care protocol provides more detailed prescribing and monitoring information and clarifies locally agreed responsibilities to enable primary care clinicians to take on clinical responsibility for prescribing, e.g. methotrexate for rheumatoid arthritis, somatostatin analogues for acromegaly.

A local committee is well placed to identify when formulary restrictions are required and which services and individual clinicians are authorized to provide restricted medicines. As experience and evidence changes these restrictions may be changed. For example a new antiarrhythmic agent may be restricted to initiation by consultant cardiologists only while its place in therapy is more clearly defined and its safety profile is uncertain.

Awareness of local safety problems

The majority of the members of DTCs and other formulary committees should be actively engaged in day-to-day prescribing and clinical practice in order to reflect safety concerns and identify potential problems as they arise. National safety alerts remain invaluable for detecting emerging adverse drug reactions and informing the NHS as a whole about product and system failures. Local committees remain a very effective way of identifying shortcomings in training, prescribing practice or service delivery where part of the remedial action required may be to restrict access to a medicine until the problem is resolved. For example, a patient developed severe hypoglycaemia following confusion between multi-dose vials of heparin and insulin. As a result one action was to remove heparin multi-dose vials from most clinical areas and purchase only pre-filled syringes. Another patient developed renal failure after being administered an incorrect dosage of intravenous iron when the prescriber confused two different iron formulations. Many formularies resist endorsing multiple agents from within a class in order to avoid similar confusion because single catastrophic errors are likely to outweigh all but major advances in ease of administration.

Healthcare acquired infections will vary over time and if an outbreak occurs within a locality then DTCs and infection control committees may well need to work closely together to change prescribing. When a more virulent *C. difficile* strain is prevalent then a temporary decision to use oral vancomycin rather than metronidazole as first line therapy may be appropriate.

Responding to growing trends

Most individual clinicians would see themselves as analytical, evidence-based and immune to marketing, but at times it looks as if medicine is as prone to fashion and advertising as any group of teenage shoppers. The fashion for intravenous NSAIDs for peri-operative analgesia had just about run its course when along came intravenous paracetamol. Many hospitals in the UK are now spending in excess of £200 000 a year on this formulation of paracetamol, with very little attempt to restrict it to only those patients who are unable for whatever reason to take oral medication.

Nor is primary care immune to fashion. Many local APCs produce a traffic light system to advise GPs on the appropriate use of medicines and seek to advise against products which carry little or no additional benefit but which come at increased cost.

Many primary care organizations have developed a list of drugs which are classified as low priority for prescribing because they represent poor value for money. Examples may include different formulations of a drug or isomers of existing products, where evidence of benefit over standard products is marginal, and some over the counter products which are considered a low priority for NHS prescribing because of limited evidence for clinical and cost effectiveness.

Local pricing arrangements

National guidance has to be read with a number of caveats. For example, NICE is not able to take unlicensed

products into account in appraisals and hence some advice (for example that on neuropathic pain) may be at variance with practice around the country. Furthermore, cost effectiveness calculations do not take into account local pricing arrangements. For example, in evaluating the most cost effective bisphosphonate for treating breast cancer patients with bone metastases, the cost effectiveness data indicate that ibandronic acid may be cost effective when compared with standard therapy of i.v. pamidronate. However, the results are very sensitive to the acquisition costs of pamidronate, and the cost applied in the study was considerably higher than that negotiated locally by the NHS hospital for generic pamidronate. This was significantly less than the minimum threshold beyond which the sensitivity analysis showed ibandronic acid not to be cost effective.

Collaborative working across the healthcare economy

Joint working at all stages in the development of a formulary is crucial for it to achieve full engagement at all levels – whether it is all clinicians within a practice for agreement of a GP practice formulary or representatives from across primary and secondary care.

The structure of most local formulary committees suggests that it is important to ensure multidisciplinary input into formulary groups and it is important that members are senior individuals who exert a direct influence on prescribing within their organization

Experience indicates that joint formularies between primary and secondary care enhance seamless care for patients, minimize problems in prescribing and enable effective management of the introduction of new drugs across the whole healthcare economy. The hard evidence that this is true, however, is lacking.

Affordability and local priorities – links with commissioners

Local committees are the final arbiters of which medicines will be endorsed and it is inescapable that they must make decisions which take into account not simply cost effectiveness but also affordability. Awareness of cost effectiveness has increased in recent years and it has had a significant influence on prescribing even though it is at times a very imprecise science [8]. NICE (and SMC and AWMSG) has achieved much in reducing irrational and inexpert decisions previously made by individual local committees but there remains a tension between what may be deemed cost effective over a period of many years for a national health service, and what is affordable over the short term by local health economies who are simultaneously charged with providing care according to need (or NICE) and living within their means. Some parts of the country have established priority setting committees which determine what services (and medicines) will be commissioned within their area [9]. At times these decisions may be at variance with national guidance or may seek to impose restrictions which create inequality of provision between different parts of the country. In times of national financial difficulty, local DTCs are likely to have to make these difficult judgements ever more frequently.

Competing Interests

There are no competing interests to declare.

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